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THE RISK TO AMERICAN CONSUMERS FROM
PRESCRIPTION DRUG DIVERSION AND
COUNTERFEITING

REPORT

BY THE

SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES



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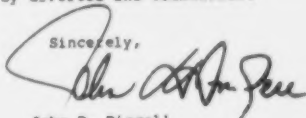
April 19, 1986

LETTER OF TRANSMITTAL

To Members of the Committee on Energy and Commerce:

This report summarizes the various techniques by which brand name pharmaceuticals of questionable potency find their way into the hands -- and, indeed, the blood streams -- of American consumers. The existence of a shadowy submarket for prescription drugs, commonly known as the "diversion market," also makes it easier to inject outright counterfeits into the United States drug distribution system. These health threats have been identified in five days of public hearings, on which this report is based. A few of my colleagues may have honest differences as to the best legislative remedies, but none of the Members of the Subcommittee disagrees as to the serious nature of the public health problems posed by diverted and counterfeit pharmaceuticals.

Sincerely,



John D. Dingell
Chairman
Subcommittee on
Oversight and Investigations

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DANGEROUS MEDICINE: THE RISK TO AMERICAN CONSUMERS FROM PRESCRIPTION DRUG DIVERSION AND COUNTERFEITING

I. INTRODUCTION

This report contains the findings and recommendations of the Oversight Subcommittee relative to the problem of prescription drug diversion. It is based on five days of public hearings and over one year of investigation by the Subcommittee staff.

The report is designed to summarize the major health and safety problems identified by the investigation and explain the Subcommittee's proposed solutions. It is not intended to repeat the detailed analysis and description contained in the June 1985 staff report entitled, "Prescription Drug Diversion and the American Consumer."¹ That report is incorporated herein by reference.

The Subcommittee's investigation has benefited greatly from the cooperation of all major elements of the pharmaceutical industry, who share the Subcommittee's deep concern about the actual and potential health and safety problems posed by diverted and counterfeit pharmaceuticals. It is the Subcommittee's firm conviction that the proposed measures are the minimum needed to prevent a serious erosion of confidence in the American pharmaceutical industry, whose estimated domestic sales in 1985 were over \$21.5 billion and whose worldwide sales exceeded \$33 billion.²

¹ "Prescription Drug Diversion and the American Consumer," Staff Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 1st Sess., Committee Print No. 99-R.

² Figures supplied by the Pharmaceutical Manufacturers Association.

II. FINDINGS

American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective. This is not to say that the shelves of the Nation's pharmacies are lined with substandard products, or that there are inadequate controls in the manufacturing process. Rather, the integrity of the distribution system is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective or even counterfeit pharmaceuticals.

Specifically, the existence and method of operation of a wholesale submarket, herein referred to as the "diversion market," prevents effective control over or even routine knowledge of the true sources of merchandise in a significant number of cases. As a result, pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers. Fortunately, while diversion is commonplace, documented instances of harmful or ineffective merchandise reaching consumers through normal retail outlets are few. This report contains a number of legislative and other recommendations that are designed to restore the integrity and control over the pharmaceutical market necessary to eliminate serious actual and potential health and safety problems.

A significant volume of pharmaceuticals are being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. The ready market for reimports has also been a catalyst for the perpetration of a continuing series of frauds against American manufacturers, and has provided the cover for the importation of counterfeit pharmaceuticals in at least two cases. Moreover, the hazards associated with reimports have forced the Food and Drug Administration (FDA) and the U.S. Customs Service to spend inspectional and other resources that are sorely needed in other areas.

The existing system of providing samples of pharmaceutical products to physicians through manufacturers' sales representatives invites abuse. The felony pleas obtained by the United States Attorney in Atlanta relative to the misuse of drug samples are but the latest episode in a long history of misuse. Samples that are improperly sold, bartered, or exchanged often end up in the secondary market, where they may easily become adulterated, misbranded or both. The propensity for misbranded sample merchandise to appear in the diversion market also makes it easier for expired or counterfeit pharmaceuticals to be introduced into the wholesale distribution system. The printing and distribution of samples, as well as efforts to police sales representatives, are costs that must be recouped by manufacturers in the sales price of regular products. At present, samples appear to be as much of a bane as they are a benefit to American pharmaceutical consumers. It would require enormous and even more costly efforts by the manufacturers, or a miraculous change in the fallibility of human beings, before the existing system of physicians' samples could be made free from abuse. Neither alternative is likely.

The resale of prescription drugs by health care institutions to persons outside the corporate umbrella of the institution -- such as a wholesaler -- helps fuel the diversion market. Such sales, which are economical only because many manufacturers sell much more cheaply to institutions than to wholesale customers, provide an unfair competitive advantage to any wholesaler or retailer that can obtain the preferentially priced goods. Moreover, the resales may well constitute fraud against the manufacturers, especially if the health care institution is allegedly purchasing the goods for its own use. In any case, the practice contributes to the lack of accountability as to product source in the secondary market.

The counterfeiting of U.S. brand name pharmaceuticals by foreign persons in foreign countries is a threat to the health and safety of consumers in those nations. In most instances, the counterfeits are subpotent or impotent, and may even be contaminated. These products steal markets from

American companies and unfairly tarnish the good name of the legitimate product and company in the foreign market. Furthermore, the counterfeit product may find its way into the United States, as has happened in at least two instances in the last two years, with obvious negative consequences.

III. RECOMMENDATIONS

The Congress should enact legislation to:

1. Ban the reimportation of pharmaceuticals produced in the United States and shipped abroad. The only general exception allowed should be for pharmaceuticals returned to the original manufacturer. The Secretary of the Department of Health and Human Services (HHS) should be given the authority to waive this prohibition for emergency medical use, only on a case by case basis.

2. Amend the Food, Drug and Cosmetic Act to make it a felony to sell, trade, barter or exchange, or offer to sell, trade, barter or exchange:

- a. pharmaceutical product samples;
- b. pharmaceutical products sold for export use only;
- c. pharmaceuticals purchased by hospitals, clinics, or other health care facilities, including agencies of state and local governments, for the exclusive use of those institutions and not intended for resale. An exception to this general ban should be made to allow for sales otherwise permitted by law to affiliated corporations in furtherance of a planned, integrated approach to the delivery of health care within a health care corporate structure, and sales by bona fide group purchasing arrangement to members; and
- d. pharmaceutical products donated or supplied at reduced prices to charitable institutions in the United States or abroad for their own institutional use.

3. Prohibit the dispensing of samples by pharmaceutical company sales representatives. The practice of providing physical samples to physicians should also be prohibited. Sample pharmaceuticals could still be provided through normal distribution channels to pharmacists, who would dispense them to patients pursuant to a doctor's prescription.

4. Require that each seller of pharmaceuticals in the wholesale market certify in writing to each buyer the source and geographic location from which they obtained the goods.

5. Direct the Secretary of HHS to promulgate regulations which establish the conditions for the interstate resale of pharmaceuticals in any state which does not license the wholesale distribution of pharmaceuticals, and establish minimum storage, handling and recordkeeping standards for wholesalers as a condition of holding such a license. The model legislation of the National Association of Boards of Pharmacy provides an excellent guide to those minimum conditions.

6. Further encourage the protection of pharmaceutical patents in Third World countries. The Trade and Tariff Act of 1984 instructed the United States Trade Representative (USTR) to examine the extent of protection for American intellectual property in his January 1, 1987 determination of whether or not developing countries should retain their eligibility for Generalized Schedule of Preferences (GSP) benefits -- duty-free entry of goods. Among other measures needed to strengthen pharmaceutical patent protection are:

- a. protection from process patent infringement in foreign countries, such as contained in S. 1543 and H.R. 1069; and
- b. reform of Section 337 of the Tariff Act of 1930 to eliminate the need to specifically prove injury in order to obtain an order excluding products which violate U.S. patents, and to permit the U.S. Customs Service to seize all goods whose entry is attempted in violation of an exclusion order.

The United States Trade Representative should:

- 1. Deny GSP benefits to any newly industrialized country which does not provide effective pharmaceutical patent protection to U.S. pharmaceutical manufacturers on January 1, 1987.
- 2. Inform all lesser developed countries that

effective laws protecting the trademarks, copyrights and patents of U.S. pharmaceutical manufacturers must be enacted by a date certain in the very near future, or GSP benefits will be discontinued until such effective protections are provided.

3. Consult with U.S. pharmaceutical manufacturers, the appropriate officials of other countries with multinational pharmaceutical companies, the World Health Organization, and officials of countries in the developing world to encourage the eradication of substandard as well as counterfeit pharmaceuticals. This may involve assistance to Third World countries to develop pharmaceutical plants which meet FDA quality control standards and to acquire research capacity in such areas as tropical diseases.

The Federal Trade Commission should:

1. Formally investigate multi-tier pricing practices in the pharmaceutical market, and especially resales by health care institutions, to determine whether these activities are anti-competitive or otherwise violate the Robinson-Patman Act.

Pharmaceutical manufacturers should:

1. Switch to unit of use packaging. This type of packaging, which is widely used in Western Europe, would tend to counter many of the abuses documented with samples. Along with a ban on reimportation, it would greatly increase control and accountability over the wholesale portion of the market. If manufacturers do not voluntarily move to a unit of use system, the Congress should consider imposing such a system.

2. Enter into discussions with the USTR and other appropriate government agencies on a program to offer technical assistance to developing countries to help upgrade their domestic manufacturing facilities and research capabilities as part of a program to ensure that patents are protected and drugs manufactured anywhere in the world are reasonably safe and effective.

3. Pharmaceutical manufacturers should be required to prominently label all of their products

intended for the restricted uses noted above.

The Congress should:

1. Review the Non-Profit Institutions Act to determine whether the statute needs modernization to more effectively achieve its original purpose in light of the changing nature and activities of non-profit institutions.

2. Closely examine the mail order dispensing of pharmaceuticals to determine whether or not the public health risks of this growing practice are reasonable.

3. Consider denying Medicaid and Medicare funds to hospitals and other health care institutions which divert drugs into the wholesale market.

The States should:

1. License and regulate the wholesale distribution of pharmaceutical drugs in a manner comparable to the regulatory attention that retail institutions presently receive. This will involve a considerable expansion of the resources devoted to inspection and other control functions. Wholesale drug firms should be required to meet the same professional standards currently required for the retail distribution of pharmaceuticals. Wholesale and retail pharmacists who deal in drugs obtained from unauthorized distributors should have their licenses forfeited regardless of whether the prosecutorial resources are available for criminal convictions.

IV. TEXT

CHAPTER I -- SAMPLING

Everyone likes to get something for nothing, and so it is with drug samples. In theory, these are provided by the pharmaceutical manufacturers to doctors so that a type of medication can be tried by a patient without having to purchase a full prescription. In practice, however, few things are truly free, and the sampling program unfortunately contains a number of pitfalls for consumers.

The Atlanta Investigation Finds Serious Sample Abuse

On August 6, 1985, the United States Attorney for the Northern District of Georgia, Mr. Larry D. Thompson, announced the initial results of a two-year undercover investigation by the Federal Bureau of Investigation (FBI) and the Georgia State Drugs and Narcotics Agency. As summarized in subsequent testimony before the Oversight Subcommittee, Mr. Thompson revealed that nearly fifty individuals and companies had been charged in criminal informations with violating various fraud statutes, as well as laws pertaining to the adulteration or misbranding of pharmaceuticals.³ Most of the persons charged have pled guilty, and additional informations have been issued as part of the continuing investigation. Many of the criminal acts involved the diversion of samples into the wholesale market for ultimate sale at retail. To do this, the sample markings and packages were routinely altered.

Mr. Thompson explained that the sample markings were removed from the tablet or pill by the use of razor blades, acetone, fingernail polish remover and

³ Statement of Larry Thompson, Hearings before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, 99th Cong., 1st Sess. (Hereinafter cited as "Hearings"), October 31, 1985.

rubbing alcohol. Moreover, the drugs themselves were often separated from their packaging and labeling, and placed into unsanitary containers such as baggies, open boxes, grocery bags, cellophane bread wrappers and used soft drink bottles. The result was that the pills or tablets became contaminated, were separated from expiration dates and could not be traced in the event of a recall. Concluded Thompson:⁴

We believe that millions of these adulterated pills were sold, and continue to be sold, across the United States for ultimate dispensing to consumers with prescriptions.... At least one drug store in every city, town and village involved in the FBI investigation was found to be dispensing such medications. These adulterated and misbranded drugs included blood pressure and heart medications, as well as thyroid pills, ulcer solutions, birth control pills and antibiotics -- almost any type of non-controlled prescription medication. (emphasis supplied)

The FBI investigation identified thirteen medical doctors who wrote manufacturers requesting pharmaceuticals for their professional use and disbursement. Instead, the samples were sold to diverters.⁵ The investigation, code named "Pharmoney," also established the fact that a number of pharmacists, sales representatives and even drug company executives were dealing in samples. In a number of cases, the samples were beyond their expiration dates, some by as much as five years.

The Misuse of Drug Samples is not New

Shocking as it was, the Pharmoney operation did not really uncover anything new. According to the

⁴ Id.

⁵ Statement of Hal Helterhoff, Hearings, October 31, 1985.

testimony of Mr. Eddie Burklow, who pled guilty in the investigation, the abuse of samples had been commonplace during his eighteen years as a sales representative and executive in the pharmaceutical industry. Mr. Burklow noted that sales representatives use samples as a marketing tool, sometimes providing excess quantities of samples to doctors or pharmacists to "sweeten" deals involving the purchase of brand name or over-the-counter drugs as an inducement to the physician to prescribe a particular company's product, or even to persuade a pharmacist to give preferred shelf space to an item. Sales representatives and doctors were also said to trade samples to pharmacists for merchandise or other drugs.⁶

Dr. John F. Schlegel, President of the American Pharmaceutical Association (APhA), the national professional society of pharmacists, testified that his association had been seriously concerned about the misuse of samples for over forty years:⁷

As early as 1941, our Association was seriously concerned about the current practices associated with drug samples. It was not drug samples per se, but the unbridled use of samples which caused [the Association's] concern. It recommended that if drug samples could not be controlled, they should be eliminated.

Dr. Schlegel recalled that the House of Delegates of the APhA, the largest deliberative body in American pharmacy, had complained about the abuse of samples many times over the years. For example, in 1968, the delegates warned that:⁸

⁶ Statement of Eddie Ronald Burklow, Hearings, September 19, 1985.

⁷ Statement of Dr. John F. Schlegel, Hearings, December 6, 1985.

⁸ Id.

Manufacturers' drug sampling as now practiced, is the source of much waste, ill will and drug diversion.... Furthermore, associated hazards of uncontrolled storage conditions, the difficulty of enacting drug recalls, drug diversion and the lack of monitoring dated drugs are of particular concern to the pharmacist.

Current Laws are Inadequate

Furthermore, existing Federal and state laws regulating the dispensing of samples are wholly inadequate. It is not a Federal offense in itself to buy, sell or trade samples. The boundaries of Federal law are crossed when samples are removed from their required packaging and labeling, or are adulterated. If the samples are controlled substances, which is usually not the case, Federal law specifies dispensing and recordkeeping requirements.⁹ According to Dr. Schlegel, in 1984 only twenty-eight states had regulations dealing with sample drugs, and even those varied widely. Only one state, Pennsylvania, explicitly requires that sample drugs be labeled with information about the name, quantity, and instructions for use before they are dispensed to a patient.¹⁰

Thus, Dr. Schlegel concluded that:¹¹

At this time, it is possible for persons not licensed or qualified to dispense drugs and unfamiliar with safe dispensing practices to acquire drug samples and dispense them to patients.

Coupon Plan Proposed as a Solution

⁹ See the Controlled Substances Act, 21 C.F.R. 1301.74(d).

¹⁰ Statement of Dr. John F. Schlegel, Hearings, December 6, 1985.

¹¹ Id.

It is time for the Congress to pass legislation that will correct the serious and long-standing abuses of drug samples. The APhA has proposed a plan that the Subcommittee believes will accomplish this goal. The plan would halt the distribution of samples by sales representatives to doctors or clinics.¹² This, in itself, would halt most of the historical abuses. It would also relieve the drug manufacturers of some of the burdens of trying to police their sales representatives, and would eliminate the virtually impossible task of keeping track of the goods once they are given to physicians.

Under the APhA plan, manufacturers could provide coupons, similar to prescription pads, to doctors, who could prescribe a sample dose to a patient. The sample prescription would be filled by a pharmacist out of regular stock. The manufacturer would replace the sample through regular shipments via normal channels. The sample would be free to the patient. The APhA envisions a dispensing fee from the manufacturer to the pharmacist. Competitive forces would tend to limit any such fee, because the pharmacist providing the sample would probably also dispense the following prescription. The manufacturer, in reimbursing the pharmacist, would discover which physicians in which areas were actually using their product, as opposed to the shotgun approach now utilized, and could more accurately and effectively use the sample as a marketing tool. The manufacturers would incur the cost of the dispensing fee, but would save the expense of printing special sample packages and markings.

Views of Other Pharmaceutical Associations

Significant interest in the sample problem has been evidenced by state pharmacy boards and other professional pharmacy associations.¹³ The Georgia

¹² Id.

¹³ See especially the testimony of Dr. Joseph M.
(Footnote continued)

Board of Pharmacy recently announced its intention to prepare legislation for the General Assembly that would ban the distribution of samples to doctors in favor of the coupon plan.¹⁴ The National Association of Boards of Pharmacy (NABP) recommends an outright ban on the manufacture or distribution of samples. NABP Executive Director Fred T. Mahaffey, in his statement to the Subcommittee, observed that:¹⁵

[W]hile the use of samples may be a strong marketing device for drug manufacturers, the opportunities that sampling provides for drug diversion and its consequential endangerment of public health far outweigh the economic benefits afforded to the manufacturers.

Mr. Mahaffey continued by noting that the basic purpose of samples is to familiarize physicians with the characteristics and uses of the drug products. This, he said, could be accomplished through information from the manufacturer. While recommending a recordkeeping system apparently modeled on the Controlled Substances Act, Mr. Mahaffey emphasized that the primary need is to increase accountability.¹⁶ Mandating the controlled substances system for all pharmaceuticals would seem to be extremely burdensome, especially when compared to the coupon system. Mr. Mahaffey did agree that if the coupon system provided accountability, then it could be "of some advantage."¹⁷

The Pharmaceutical Manufacturers Favor Sampling

13(continued)

Oddis, American Society of Hospital Pharmacists, Hearings, December 6, 1985.

¹⁴ Atlanta Constitution, January 8, 1986.

¹⁵ Statement of Fred T. Mahaffey, National Association of Boards of Pharmacy, Hearings, December 6, 1985.

¹⁶ Id.

¹⁷ Id.

As might be expected, the primary arguments in favor of retaining the current sampling system were raised by the Pharmaceutical Manufacturers Association (PMA). Mr. Bruce J. Brennan, Senior Vice President and General Counsel, indicated that samples were typically provided to start the patient on medication before a prescription was filled at a pharmacy. Such samples, said Mr. Brennan, enable the physician to immediately evaluate the effects of the medication.

It is the impression of the Subcommittee, admittedly based on less than complete evidence, that most samples are taken by the patient at home rather than at the doctor's office. Moreover, even if taken on the spot, it would take many hours before the therapeutic effect of most medications could be fully evaluated. Obtaining samples at a pharmacy, and then reporting their effect via the telephone or in person, does not appear to be especially burdensome or illogical. In cases of life threatening illnesses, the patient should go to the emergency room. Samples are not designed for such situations, and not all doctors even have samples.

Mr. Brennan testified that safeguards against sample abuse exist, including company procedures and policies, a requirement that samples be provided pursuant to a written request, labeling and marking. Of course, none of these have been effective in preventing the shocking abuses recently documented by the U.S. Attorney in Atlanta. Moreover, the coupon system would preserve the primary benefit of samples -- a free starter dose to test the effectiveness of the medication. Thus, it is the Subcommittee's view that the coupon system would achieve the PMA's goal that:18

Legislative remedies to curb abuse should be directed at the root of the problem -- unscrupulous pharmaceutical representatives,

18 Statement of Bruce J. Brennan, Pharmaceutical Manufacturers Association, Hearings, December 6, 1985.

health care practitioners and pharmacists -- and should not penalize the many patients who benefit from the use of samples.

Of course, neither the coupon system nor any other program that preserves samples will stop all abuse. Thus, the Subcommittee strongly endorses the PMA's suggestion that legislation be enacted to prohibit the purchase or sale of samples.¹⁹

Unit of Use Packaging

The Subcommittee's final legislative recommendations on sampling will be evaluated in light of one other broad alternative -- unit of use packaging, in which the pharmaceutical product is not packaged in bulk, but in the size appropriate for dispensing to consumers. According to Mr. Brennan's testimony, the PMA Board is now considering a study of manufacturer dispensed packaging.²⁰

In theory, such packaging would make it much more difficult to sell samples and other special purpose pharmaceuticals at retail. Instead of the current practice of dispensing the pills or tablets in plastic vials after their removal from sample packaging, the would-be sellers would have to put the drugs into regular manufacturers' packages. The cost and difficulty of duplicating such packages would obviously reduce the incentive to deal in samples and other "not for retail sale" pharmaceuticals. However, it is also important to remember that the counterfeit Ovulen 21 birth control pills were placed in bogus Searle packaging that was produced to resemble the original exactly, as was the counterfeit Ceclor, which was placed in Lilly capsules and packaging.

¹⁹ Id.

²⁰ Id.

CHAPTER II -- IMMUNIZING THE DIVERSION MARKET

Participants in the diversion market cover a broad range in size, volume of sales, and type of merchandise.²¹ In some cases, the firm's entire business is to buy and sell diverted merchandise, while in other cases only a small percentage of the company's activities involve such goods. One well-known company, Med Sales of Hollywood, Florida, sold \$35 million worth of diverted pharmaceuticals in 1984 to 250 accounts, most of which were wholesalers and chain drug stores.²² Another company, Interstate Cigar of Westbury, New York, which deals more in health and beauty aids than prescription drugs, was reported to have sales of \$60 million in 1978.²³ Interstate's facilities include a 100,000 square foot warehouse at Westbury, large warehouses in Savannah, Georgia and Los Angeles, California, and a fleet of tractor trailers. A wholly-owned firm, L.S. Amster, is also located near Interstate's main facilities in Westbury.²⁴

Diverted Merchandise Comes from Legal and Illegal Sources

The sources of supply to the diversion market are varied. Some are legal and some are not. Illegal sources include counterfeits, stolen goods, drugs obtained through fraud or false representations, and samples. Legal sources include drugs bought at special prices or prior to price increases and resold when the price goes up, dump sales by manufacturers of overstock or discontinued items, promotional sales, and special price sales for large volume purchases. By the time the pharmaceuticals reach the retail

²¹ Diverted merchandise is generally defined as any brand name product that is not obtained directly from the manufacturer or an authorized distributor.

²² Drug Topics, August 19, 1985, p. 14.

²³ Chain Drug Store Age, Drug Edition, July 1978.

²⁴ Id.

pharmacy, these sources of supply become commingled.

One of the traditional sources of diverted goods has been the sales force of the manufacturers themselves. As explained in the testimony of Stanley Kowitt, Eddie Burklow and Stephen Eckstein,²⁵ salespeople attempting to meet quotas, increase commissions or defraud the company for personal gain will engage in a variety of schemes which result in goods flowing into the diversion market.

Drugs diverted from health care institutions, especially hospitals, are another important source of merchandise for the secondary market. One of the leading practitioners of this appears to be Marchar Laboratories, a Brea, California wholesaler, which has publicly indicated that it has contracted with at least fourteen hospitals to order drugs in excess of the needs of the hospitals. The drugs are then resold to Marchar for eventual retail sale.²⁶ The Subcommittee staff has had several lively discussions with counsel for Marchar as to whether or not such resales violate the Robinson-Patman Act.

Leaving this question aside, the Subcommittee believes that resales to wholesalers by health care institutions, whether these institutions are for profit or non-profit, is clearly an undesirable practice. Because the institutions obtain discriminatorily low prices on many prescription medications, resales of these items clearly disadvantage other wholesalers and retailers who do not have access to similarly priced goods. Competitive pressure is thus brought to bear on businesses which choose not to deal with diverters. Further, the resales may well constitute a fraudulent and deceptive act against the seller, usually a manufacturer, by both the hospital and Marchar. The Subcommittee requested, by letter, information as to the scope and volume of these purchases from Marchar. The company has not responded voluntarily, apparently

²⁵ See Hearings, September 19, 1985.

²⁶ Marchar's statement is retained in the Subcommittee files.

on the advice of their criminal counsel, who has advised the Subcommittee staff that the U.S. Attorney in Atlanta has expressed a desire to talk to Marchar regarding certain of their pharmaceutical purchases.

Because of the possible criminal proceeding, the Subcommittee has not required Marchar to furnish the requested information. However, the Subcommittee has learned more than enough about institutional diversion to conclude that the practice should be prohibited.

Company Size is no Guarantee of Quality

The larger firms tend to deal in volume, rarely handling orders below case lots, and generally do not purchase samples. However, mere size is no guarantee of quality. Several of the larger, well-known diversion firms bought counterfeit Ovulen 21 in 1983-84. Despite this experience, some of these very same firms also bought counterfeit Ceclor, an Eli Lilly antibiotic, that was shipped into the U.S. from Hong Kong and Singapore in the fall of 1985.

Moreover, one of the largest pharmaceutical wholesalers in the Midwest, Bindley Western of Indianapolis, Indiana, a publicly-traded company whose sales volume is several hundred millions of dollars annually, has been involved literally from top to bottom in illegal diversion activities, including samples. On October 29, 1985, the former Executive Vice President was charged with mail and wire fraud by the U.S. Attorney in Atlanta. The "Pharmoney" investigation conducted by Federal authorities in that city had already obtained guilty pleas on charges of drug adulteration, misbranding and mail fraud from former Bindley employees, including a Vice President, the General Manager, and the head of sales of the Atlanta office. On November 8, 1985, agents from the FBI, the Internal Revenue Service and the Drug Enforcement Administration executed a search warrant at Bindley's corporate headquarters. It was also revealed that the firm's Chairman, William E. Bindley, and its Vice President and Treasurer, were subjects of the continuing grand jury investigation in Atlanta.²⁷

Many of the individuals who have been the subject of criminal charges in the Atlanta investigation have

been associated with small or medium-sized companies, and a number of doctors and pharmacists have also pled guilty. The U.S. Attorney has also indicated that approximately forty more individuals and companies are targets of the investigation. Thus, abuses associated with drug diversion clearly bear no relationship to the size, volume, or type of merchandise handled by the company.

The corollary of this situation is that most wholesalers and retailers cannot, with absolute certainty, protect themselves against buying pharmaceuticals that may be adulterated, subpotent or ineffective. The widespread availability of merchandise from secondary sources and the highly competitive nature of the wholesale and retail pharmaceutical markets create tremendous economic pressure to obtain merchandise at the lowest possible price. For a company to do otherwise is to lose market share and, over time, go out of business.

The realities of the wholesale marketplace have combined to create a system in which a large amount of attractively priced pharmaceuticals are constantly available, some of which are not safe or effective. The physical movement, conditions of storage, and, in some cases, even the origin of much of this merchandise is unknown to the first, second or third level buyer, who in effect plays a form of Russian roulette. This situation cannot be allowed to continue. If the wholesale market is not immunized against the threat of ineffective or adulterated drugs, serious health consequences will result, consumer confidence will be undermined, and relatively draconian measures will likely be mandated by regulatory authorities.

The Diversion Market Lacks Accountability

The basic problem with merchandise in the secondary market is the lack of accountability. The

²⁷ The Wall Street Journal, November 12, 1985, p. 10.

same wholesaler that buys at a volume discount or takes advantage of a special manufacturers' offer may also buy subpotent or counterfeit drugs from overseas. At present, purchasers of diverted goods subsequent to the first purchaser usually do not know how or from where the goods were obtained. If such information were available, it is the Subcommittee's belief that the risks and uncertainties associated with goods in the secondary market would be greatly reduced. Moreover, the introduction of counterfeits, stolen merchandise or samples would be much more difficult.

Finally, in contrast to the current situation where the purchaser can claim that they should not be held responsible for substandard pharmaceuticals because the seller did not tell them the source, the liability for questionable purchases and sales can be more easily placed where it belongs. Therefore, the Subcommittee recommends that sellers of prescription drugs be required to certify in writing to purchasers the source and place from which they obtained the drugs. False statements would constitute civil fraud, and willfully or knowingly providing misinformation would be a criminal offense.

Two companies that buy diverted drugs, one a large chain drug store and the other a volume wholesaler, have voluntarily instituted a program by which diverted pharmaceuticals are tested by an independent laboratory before they are resold. Such programs are private sector attempts to mitigate the known risks associated with diverted drugs. The testing programs have disadvantages in terms of cost and delay. It seems preferable to the Subcommittee to deal more directly with the underlying problems in the distribution system than to mandate a massive and probably unenforceable, "Band-Aid" type solution in the form of a national testing requirement.

CHAPTER III -- COUNTERFEITING AND REIMPORTATION

In both 1984 and 1985, one case of the shipment of foreign source counterfeit pharmaceuticals into the United States was discovered. In 1984, over one million counterfeits of G.D. Searle's Ovulen 21 birth control pills were found to have been shipped to Miami and New York from Panama. In 1985, 1800 bottles of Eli Lilly's antibiotic Ceclor capsules were entered in Miami and Boston from Singapore. The Ceclor contained Eli Lilly's active ingredient, but the capsules, labels, lot numbers and packaging were all fake. The actual source of the counterfeits is unknown.

Counterfeit Pharmaceuticals Were Cleared by the Food and Drug Administration

Both of the counterfeits involved multiple shipments, all of which were declared to Customs and granted entry by the FDA. One reason that FDA was not suspicious of such shipments was because the reimportation of brand name American pharmaceuticals from South America, Asia or Africa was commonplace. As documented in the June 1985 Subcommittee report, a continuing series of frauds have been perpetrated on American drug manufacturers with a similar objective -- to obtain brand name pharmaceuticals at prices low enough to cover the cost of reimportation and still leave a profit margin after resale to a diverter.

Reimportations Provide Cover for Counterfeits

In some cases, company sales personnel appear to have been eager to make the sale and not particularly concerned with the danger of diversion -- especially if the goods reappeared in someone else's territory.²⁸ In other cases, the overseas sales representative of the U.S. company was involved in or at least unconcerned about the diversion.²⁹ In all such cases,

²⁸ See testimony of Stanley Kowitt and Eddie Burklow, Hearings, September 19, 1985.

the goods flowed back into the U.S. wholesale market. Such goods may have been exposed to extremes of temperature and lost potency or become adulterated in the course of their handling and movement in foreign lands. But even if the pharmaceuticals were properly handled, the very existence of the market for reimported goods provides the perfect cover for foreign counterfeits.

Furthermore, the situation overseas appears to be worsening. While some countries, notably Taiwan and Korea, may be moving toward some form of product patent protection for pharmaceuticals, others such as Thailand seem to actually encourage the local production of subpotent and even toxic pharmaceuticals.³⁰ Under the guise of providing low cost pharmaceuticals to the population, pharmaceuticals are specifically excluded from product patent protection. The Subcommittee staff has been told that "generic" substitutes are available in Thailand within two weeks after the patented drug is approved for sale.

This situation might seem justifiable on some non-economic grounds except that Thai manufacturers appear to have the same production standards reputed to American heroin dealers, i.e. half the active ingredient makes for twice as much product, a quarter of the active ingredient will produce four times the quantity, etc.

Smith, Klein and Beckman analyzed the "generic" Tagamet legally available in Thailand and concluded that potency ranged from five percent to eighty percent of their product, with some generics containing "unidentified" substances. While these products are not labeled "Tagamet," the pills are designed to look almost identical. Furthermore, counterfeit "Tagamet" has already been detected in

29 See testimony of Stephen Eckstein, Hearings, September 19, 1985.

30 Subcommittee staff discussions with Thai and American government officials and manufacturers' representatives.

Hong Kong.³¹

Clearly, the basic medicines necessary to sustain life should be available and affordable in developing countries. These medicines have been identified by the World Health Organization and are no longer under patent. American and other research-based, multinational drug firms should be allowed to supply new drugs with a certainty that they will be able to recapture a reasonable proportion of their research and marketing cost in these countries. Because of the lack of patent protection, little research is conducted on some diseases most common in tropical climates.

There would appear to be a concurrence on needs. Developing countries need cheap, but safe and effective drugs. Multinational manufacturers need protection for their very costly intellectual property. Everyone needs to be able to purchase genuine medication anywhere in the world. The Subcommittee believes that there exists a basis for reciprocal solutions and that the appropriate officials in countries in the developing and developed world should, in consultation with the multinational drug firms, strive to achieve and implement these solutions quickly.

The threat of the loss of GSP privileges has already borne some fruit in several of the newly industrialized countries. However, the threat of removal of GSP privileges to poorer countries, which may not yet be major exporters to the United States, is not likely to have the same impact. Moreover, once those privileges have been revoked, the leverage for encouraging effective intellectual property protection is removed, but the problem of the possible importation of substandard or dangerous counterfeit pharmaceuticals remains.

³¹ The Smith, Klein and Beckman data is retained in the Subcommittee files. The Hong Kong Customs Department has promised to supply the Subcommittee with details of that case. Those documents will be retained in the Subcommittee files.

As discussed below, the Subcommittee believes that prohibiting the reimportation of pharmaceuticals identified as American Goods Returned will substantially reduce this threat. However, as is the case with controlled substances, routes will be found if the potential profit is high enough. The lower the potency of the drug, the higher the profit margin. Therefore, it remains in the interest of the United States and our research-based drug companies to encourage the production of safe and effective pharmaceuticals worldwide.

Food and Drug Administration Inspection Has Been Strengthened

The Subcommittee's investigation has determined that FDA inspection and testing of pharmaceutical reimportations were seriously inadequate prior to September 1985. At the urging of the Subcommittee, coordination between FDA and the Customs Service was improved and FDA initiated a much stricter inspection program. Now, complete documentation is required before goods can be entered as American Goods Returned. Testing at an independent laboratory is also required for any shipment whose packaging appears to have been damaged or is suspect for any other reason.

The increased vigilance by the FDA should make it very difficult to bring foreign counterfeit pharmaceuticals into the U.S. through normal channels. Between September 15 and December 31, 1985, the FDA inspected 146 separate entries of returned pharmaceuticals. Four shipments of counterfeits, all Ceclor, were discovered. However, the increased checking by the FDA will not significantly reduce the incentive of diverters to defraud manufacturers. The enhanced inspection program will require the continued expenditure of scarce resources by the FDA, and the diversion of effort from other important tasks.

Reimports Provide Little Benefit

Because there is little or no significant benefit to consumers from pharmaceutical reimportation, and

there are obvious costs in terms of health and safety risks and the utilization of scarce FDA resources, the Subcommittee believes that such reimportations should be prohibited with strictly limited exceptions.

ADDITIONAL VIEWS OF THE HONORABLE JAMES T. BROYHILL AND
THOMAS J. BLILEY

The diversion of prescription drugs is a serious problem. While we support most of the Subcommittee's conclusions and recommendations, we are concerned about the far-reaching recommendations with respect to the practice of drug sampling. We are concerned that the recommendations regarding sampling do violence not only to what has been a long-standing and acceptable marketing practice of pharmaceutical manufacturers, but what is also an effective and integral part of the practice of medicine for prescribing physicians throughout the country.

This Subcommittee should not propose the elimination of a system which clearly provides extensive medical benefits to both patient and physician until less disruptive action has been taken and the effect of that action carefully and thoroughly evaluated. Particularly, we ought not prescribe a replacement system which has such potential for harm, as does a coupon system, without a much more thorough review of this particular aspect of the diversion problem.

As the testimony of the Pharmaceutical Manufacturers Association at the December 6, 1985 hearing indicated, samples are provided by many pharmaceutical companies, particularly of newly introduced products, in response to requests. Typically, a small number of doses is given to start a patient on medication before a prescription is filled at a pharmacy.

No one questions that diversion has occurred by abuse of the sampling system by sales representatives of pharmaceutical manufacturers, physicians and pharmacists. Nor can one reasonably question the medical benefits which flow from sampling. Most parents, for example have likely experienced a late night trip to a doctor with a sick child. They probably would not find the prospect of a trip to the pharmacy for medicine nearly as comforting as, as is often the case, receiving medication for that child immediately from the attending physician.

We are concerned that the Subcommittee has not adequately considered the ramifications this recommendation may have on those who currently benefit the most from sampling.

Patient compliance will be negatively impacted if samples are banned and a coupon system adopted. Some patients may not take the time or may find it inconvenient to obtain their starter medication from a pharmacy in a timely manner, whereas, they would take their medication as scheduled by the physician if samples were given to them in the physician's office. This is particularly true for those patients in the inner city and in rural areas where it may be difficult or time consuming to travel to a pharmacy. If the starter medication is not immediately available, there is a distinct possibility that prescribed medication will not be taken at all.

Indigent patients' access to pharmaceutical services may be limited. Currently, some individual patients who are not on the medicaid rolls are given larger quantities of samples by physicians to help defray the cost, since chances are the patient would not get the prescription filled if he had to pay the full amount. The alternative under the proposed coupon system would be to have multiple coupons redeemed. The practicality of this cumbersome procedure is questionable.

Patients may be deprived of free starter doses if the coupon system is not accepted by the pharmaceutical industry or any of its segments. If neither samples nor a coupon system are available this could present serious problems for patients, physicians and pharmacists. Patients would have to pay for the starter quantity and then if intolerance developed, either the patient would lose his money or the pharmacist would have to refund the money. A bad experience of this nature could discourage patients from getting future prescriptions filled.

The new system could adversely impact on the physician patient relationship. Under the coupon system, the physician may not know exactly what product the patient received, that is, what manufacturer's product was dispensed. The availability of samples would continue to give the physician more flexibility in experimenting with different products until the optimal therapy was found. Under the coupon system, the patient would not only have to make multiple trips to the physician's office but to the pharmacy as well.

Samples provide an educational feature to the physician. The handling of samples allows the physician to become familiar with the appearance of different products. This experience can be very useful in emergency situations where the medication has to be identified very quickly.

Cost of medication to the patient would increase under the coupon system. Administering and auditing a coupon program would be very time consuming, if not impossible, and costly to the pharmaceutical industry. Likewise, it would place a burden on the pharmacy profession with large amounts of paper work. The physician would also have difficulty handling a coupon system because of the massive number of coupons that would be available to cover each company's products.

Samples should be better controlled nationally. Rather than banning sampling which has proven over the years to be advantageous to the consumer, physician, and pharmaceutical industry, more stringent controls on a national basis would be in order. An industry-wide code of good sampling practices would provide an effective and reasonable alternative to banning sampling. Such a program could be monitored by industry trade groups and would provide a greater benefit to the health care consumer than an outright ban. More stringent record-keeping reflecting exactly what the sales representatives received, what the physician ordered, and what the physician received would go a long way toward curbing sampling abuse.

Samples are a very small part of the overall diversion problem. Considering the total diversion problem in terms of volume of drugs that fall into unauthorized hands, samples are a very small part of this problem. To ban samples would be overkill, especially considering the value of samples to the patient. More stringent controls and the establishment of adequate penalties for those who abuse samples should bring samples misuse under control and allow authorities to concentrate on the major diversion problems.

The acceptance of a coupon system is, at best, questionable. Coupon programs have been used in the past by the pharmaceutical industry and have met with limited success. They have not been well received by the physician. The proposed coupon program is largely speculative, and no scientific data has been presented by the proponents to demonstrate that such a system is workable, or will be of greater benefit to the health-care consumer than the current sampling system.

Coupon fraud would take many forms. Outright counterfeiting of coupons could present serious problems as would false claims made for prescription medicine not dispensed. Under the coupon system, the manufacturer has no way of knowing if a starter prescription is filled with its pro-

duct and would still be required to replace the quantity dispensed plus pay the professional fee. In this situation, the potential exists for the patient not to get what the doctor intended, and the doctor may not know what product the patient received. The latter could present a problem if an allergic reaction or some other adverse reaction should occur and the physician is called on to make treatment decisions.

This Subcommittee should not recommend disrupting a system which affords such obvious benefits. We should not disrupt a system that provides immediate therapy when needed. And this Subcommittee should not recommend replacing the present system of sampling with a new system which is awkward and which is unwieldy at best and which affords perhaps even greater opportunities for fraud and abuse than the current system. The coupon system proposed by the APhA eliminates a major benefit of sampling -- immediate therapy.

Instead of banning the distribution of samples, we should see what effect the Subcommittee's recommendation to make sample diversion a felony, together with a voluntary industry crackdown on abuse, has on the problem. We should give all of the affected groups and professions an opportunity to work within their organizations as well as cooperatively to deal with the diversion of drug samples.

After enactment of such a prohibition on the buying, selling or bartering of samples and a reasonable period for observing its effect, it would be appropriate for this Subcommittee to again examine the situation and to decide at that time, after hearing from all parties interested in this matter including the medical professions, which did not testify at our hearing as to their position on imposing additional restriction as those proposed by this report.

The Subcommittee should by and large be commended for a thorough investigation of the problem of drug diversion. We strongly support most of the conclusions and recommendations in this report. We are concerned that too much attention has been given to attempting to solve the sampling problem without adequately considering all of the ramifications of the proposed remedy. It would be our strong recommendation that any legislative committee seriously consider those effects before proceeding with legislation to ban sampling.

We also understand that there is some industry concern over requiring "unit of use" packaging. We do not consider

this concern to be a major difficulty, but we would recommend that any legislative subcommittee receive thorough testimony on this issue.

We support the Subcommittee and its work on the drug diversion issue. We hope that appropriate legislation can be approved quickly after appropriate further investigation of the two issues we have discussed above.

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